JAN 1 0 2002

510K SUMMARY – MISONIX IRRIGATION SYSTEM MODEL BC20P

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMSA 1990 and 21CFR 807.92.

The assigned 510(k) number is: K013417

1. Submitter's Identification

Name:	MISONIX, INC.
Address:	1938 New Highway, Farmingdale, NY 11735
Telephone Number:	(516) 694-9555
Contact Person:	Ronald R. Manna
Date Prepared:	5 October 2001
Date Revised:	8 February 2002

2. Name of Device

Proprietary Name:	Misonix Irrigation System (Model BC20P)
Common / Usual Name:	BC20P
Classification Name:	Pump, Irrigation
Product Code:	GBX

3. Predicate Device Information

Predicate Device	LySonix Irrigation System K974233

4. Device Description:

The Misonix Irrigation System (BC20P) is a liquid transfer system. It is designed to utilize standard or custom tubing sets, which mate to IV bottles or bags, open reservoirs or other liquid canisters. The liquid is drawn through the pump head and then pressurized, allowing the liquid to be transferred from the source. The outlet of the tube set may be connected to a cannula or other orifice to allow flushing and cleaning of the site. It can be used to refill small containers from a larger reservoir. It is not intended for drug delivery or the administration of parenteral fluids.

5. Intended Use:

The Misonix Irrigation System Model BC20P is indicated for use in the delivery of fluids in the following surgical specialties:

General Surgical Procedures

6. Comparison to Predicate Device:

The Misonix Irrigation System is identical in all aspects to the LySonix Irrigation System since both units have been designed and manufactured to the same specifications by Misonix.

7. **Discussions of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Output Power Measurements (No Load to Maximum Load)
Irrigation Flowrate Measurements
Life Tests
Vacuum Flowrate and Pressure Measurements
Input Power Measurements
EMI Tests
Dielectric Tests on Mains Circuits
Patient Current Leakage and Patient Sink Current Measurements
Power Line Ground Leakage Measurements
Dielectric Tests on Patient Circuits.

8. **Discussions of Clinical Tests Performed**

N/A

9. **Conclusions**

Based upon an analysis of the operating characteristic specifications, Output of Engineering Tests, Hazard Analysis, Voluntary Consensus Standard Investigations and the designing activities, Misonix, Inc. has concluded that the Misonix Irrigation System is substantially equivalent to the LySonix Irrigation System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 0 2002

Misonix, Inc.
Albert F. Clancy, Jr.
Manager, QA/RA
1938 New Highway
Farmingdale, New York 11735

Re: K013417
Trade Name: Misonix Irrigation System (Model BC20P)
Regulation Number: 878.4200; 876.5220
Regulation Name: Introduction/Drainage Catheter and Accessories;
Colonic Irrigation System
Regulatory Class: II
Product Code: GBX; KPL
Dated: October 5, 2001
Received: October 15, 2001

Dear Mr. Clancy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE

510k Number: K013417

Device Name: Misonix Irrigation System (Model BC20P)

Indications for Use/ Intended Use:

The Misonix Irrigation System Model BC20P is indicated for use in the delivery of fluids in the following surgical specialties:

General Surgical Procedures

The Misonix Irrigation System (BC20P) is not intended for the administration of parenteral fluids, infusion of drugs or for any life sustaining purposes.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restora
and Neurological Devices

510(k) Number K013417

Prescription Use ✓ OR Over the Counter Use _____
(Per 21CRF 801.109)